UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BLUE CROSS BLUE SHIELD ASSOCIATION, *ET AL.*	**CIVIL ACTION NO. 2:13-CV-4663-JS**
PLAINTIFFS,	**REDACTED FILING**
V.	
GLAXOSMITHKLINE LLC,	
DEFENDANT.	

DEFENDANT'S REPLY MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO EXCLUDE EXPERT TESTIMONY OF PHILIP RUSS, DRS. DAVID KESSLER, MATTHEW PERRI, STEPHEN SCHONDELMEYER, AND RENA CONTI

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I. ARGUMENT

A. Mr. Philip Russ

Mr. Russ's opinion should be excluded because it is not relevant to the question the jury will be asked to decide, which, according to the Court's order denying GSK's motion to dismiss, is whether plaintiffs can "prove that the nature of [the cGMP] violations had a material impact on the drugs for which they paid." 11/9/16 Order, p. 11 [Dkt. 105]. Plaintiffs do not argue that Mr. Russ's opinion is relevant to that question. They simply insist that is the wrong question.

[redacted]

[redacted] Citing the Court's 12(b)(6) opinion, they insist the issue for the jury is whether GSK could "assure" that the drugs ***were not*** impacted. *Id.* Thus, plaintiffs argue that they must show only that there was a "material impact" on "GSK's assurances," even if there was no impact on the drugs themselves.

The dispute between the parties regarding what question will be put to the jury involves a pure matter of law. And the Court has already resolved it. Because plaintiffs must prove that the cGMP violations "had a material impact ***on the drugs*** for which they paid," 11/9/16 Order, p. 11 [Dkt. 105] (emphasis added), Mr. Russ's generic opinion must be excluded as irrelevant.

[redacted]

[redacted]

[redacted] FDA did not allow "worthless" drugs to be shipped to consumers. FDA did exactly what its own guidance says is required – it made a determination about the impact on specific products. That is why FDA allowed continued distribution of all other products in 2005 even as it seized ***two specific products*** based on ***product-specific issues*** that were ***expressly identified on FDA's website*** at the time of the seizure.[1] That is precisely the analysis Mr. Russ failed to do.

[redacted]

[1] *See* FDA Q&A (GSK SOF Ex. 75), Question 4, identifying the "manufacturing problems that resulted in FDA's seizure action" for Paxil CR (tablets "can split apart") and Avandamet (may not be "manufactured uniformly" and "may not have an accurate dose of rosiglitazone").

[redacted]

[redacted] Mr. Russ's opinion is not only irrelevant to the question before the jury, it will serve to confuse and mislead the jury.

[redacted]

Mr. Russ's testimony will not be "helpful" to the jury in determining which, if any, of the 17 At-Issue Drugs were "materially impacted," or when during the six year period they were impacted. Instead, it will only confuse the jury. As such, his opinion should be excluded.

[redacted]

B. Dr. David Kessler

[redacted] They neither offer case authority for this distinction nor distinguish those cases cited by GSK excluding experts who opine that something is material, for offering a legal opinion. Nor can plaintiffs find any support for their position, as the word "material" is "no doubt, a legal term of art," *United States v. Ceccerelli*, 350 F. Supp. 475, 477 (W.D. Pa. 1972); *see also United States v. Ramos*, 45 F.3d 1519, 1523 (11th Cir. 1995) ("Materiality is a legal term describing a relationship between [] two sets of facts.")

When an expert defines a term differently than does the law, the danger of confusion and prejudice to the jury outweighs the likelihood that the testimony will be useful. *See, e.g., United States SEC v. Mudd*, 2016 U.S. Dist. LEXIS 59273, at *25 (S.D.N.Y. May 3, 2016) (excluding expert testimony "likely to confuse and mislead the jury on the issue of materiality, a distinct legal concept with a distinct legal definition."). [redacted]

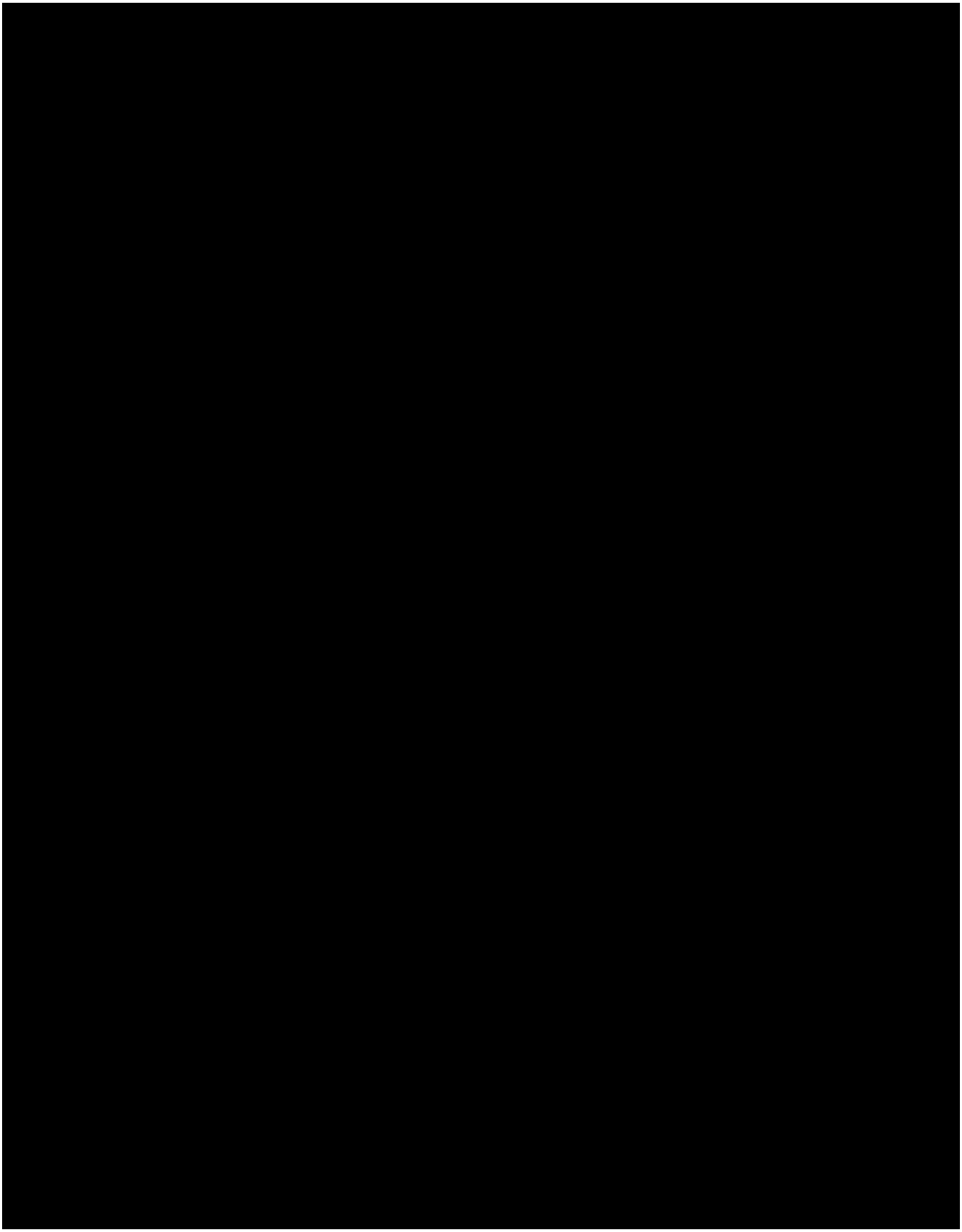
Second, [redacted]

[redacted] *See United States v. Libutti*, 1994 U.S. Dist. LEXIS 19913, at *23-24 (D.N.J. Feb. 8, 1994) (excluding expert testimony when opinion "not derived from a reliable and demonstrable body of knowledge in the specialized field."). Contrary to plaintiffs' contention, this is not a battle of the experts, but a circumstance in which an expert has invented a standard. [redacted]

Accordingly, GSK respectfully requests this Court exclude Dr. Kessler's testimony concerning whether the alleged cGMP violations had a "material impact" on the At-Issue Drugs.

C. Dr. Matthew Perri

Plaintiffs' arguments that the Court should not exclude Dr. Perri's report and testimony consist mostly of misdirection. They seek to explain away *United States v. AseraCare, Inc.*, in which the court excluded Dr. Perri's opinion, as grounded in his lack of experience in the hospice industry, ignoring that court's rulings that are directly on point here: (1) Dr. Perri "merely recite[d] the documentary evidence and testimony" regarding "marketing and business practices" before making "conclusory statements" and (2) he made "no attempt to explain how his universal principles of marketing' methodology" informed his opinion. 2014 U.S. Dist. LEXIS 167970, at *29-30 (N.D. Ala. Dec. 4, 2014), holding *aff'd*, 2014 U.S. Dist. LEXIS 191640 (N.D. Ala. Dec. 19, 2014). The same problems infect his opinion here.



Daubert requires that experts do more than simply parrot opinions or information provided by counsel. *Fail-Safe, L.L.C. v. A.O. Smith Corp.*, 744 F. Supp. 2d 870, 889 (E.D. Wis. 2010) (excluding expert who "appear[ed] to be merely parroting the predictions of [defendants] executives"); *Cordoves v. Miami-Dade County*, 104 F. Supp. 3d 1350, 1363 (S.D. Fla. 2015) ("*ipse dixit* and parroting of lay witness testimony [is] certainly not a reliable methodology"). At bottom, Plaintiffs' effort to re-frame and rehabilitate Dr. Perri's testimony falls short of the mark. He demonstrated both in his reports and his deposition that he is no more than a mouthpiece for their theory of the case, and his opinion should be excluded.

D. Dr. Stephen Schondelmeyer

GSK moved to exclude the expert testimony of Dr. Schondelmeyer as unreliable for three reasons: (1) he performed no economic analysis to support his economic opinion; (2) rather than

performing any economic analysis, he opined on plaintiffs' state of mind; and (3) he formed his opinion without reviewing any evidence. Plaintiffs' response to these three arguments is either to concede the point or to misstate Dr. Schondelmeyer's opinion and the basis for it.

[redacted]

On this ground alone, Dr. Schondelmeyer's opinion should be excluded.

[redacted]

Dr. Schondelmeyer has been chastised for this *same* practice previously. *Healthpoint, Ltd. v. Ethex Corp.*, 2001 WL 36101315, at *3 (W.D. Tex. Sept. 7, 2001) (excluding Dr. Schondelmeyer's testimony on state of mind). [redacted]

[redacted]

[redacted]

[redacted]

[redacted] as in *HealthPoint*, his speculative testimony on state of mind should be excluded. 2001 WL 36101315, at *3 (state of mind "is a question for the jury to decide" and not the proper subject of expert opinion).

[redacted] And, as with Dr. Schondelmeyer's other flaws, courts have criticized his opinions on this basis. *See, e.g., J.B.D.L. Corp. v. Wyeth-Ayerst Labs., Inc.*, 2005 U.S. Dist. LEXIS 11676, at *53 (S.D. Ohio June 13, 2005) (criticizing Dr. Schondelmeyer's opinion for failing to cite any objective study and ignoring contradictory record evidence). [redacted]

The court may reject testimony by an expert who fails to list his supposed sources because this leaves the "court ill-equipped to examine precisely what data [the expert] gleaned from them." *Total Containment, Inc. v. Dayco Prods.*, 2001 U.S. Dist. LEXIS 15838, at *22 (E.D. Pa. Sept. 6, 2001). [redacted]

[redacted] Thus the cases plaintiffs cite are inapposite – [redacted][5]

[redacted] After-the-fact review of evidence is an impermissible method of forming an expert opinion. *See Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502-03 (9th Cir. 1994) ("Coming to a firm conclusion first and then doing research to support it is the antithesis of [the scientific] method.").

[redacted]

[5]*Terry v. McNeil-PPC, Inc.*, 2016 U.S. Dist. LEXIS 26603, at *14 (E.D. Pa. Mar. 2, 2016) (relying on "company documents"); *Wonderland Nurserygoods Co. v. Thorley Indus., LLC*, 2013 U.S. Dist. LEXIS 171399 (W.D. Pa. Dec. 5, 2013) (relying on interviews with company personnel); *CB Aviation, LLC v. Hawker Beechcraft Corp.*, 2011 U.S. Dist. LEXIS 128918 (E.D. Pa. Nov. 8, 2011) (relying on interview with witness and trade publication containing valuation data); *In re Sulfuric Acid Antitrust Litig.*, 235 F.R.D. 646 (N.D. Ill. 2006) (relying on pricing data compiled by another expert).

[redacted] As in *Floorgraphics*, plaintiffs cannot supplant their direct testimony with contradictory expert opinions. 546 F. Supp. 2d 155, 179 (D.N.J. 2008). Dr. Schondelmeyer's unsupported speculative testimony should be excluded.

E. Dr. Rena Conti

[redacted][6][redacted]

[redacted]

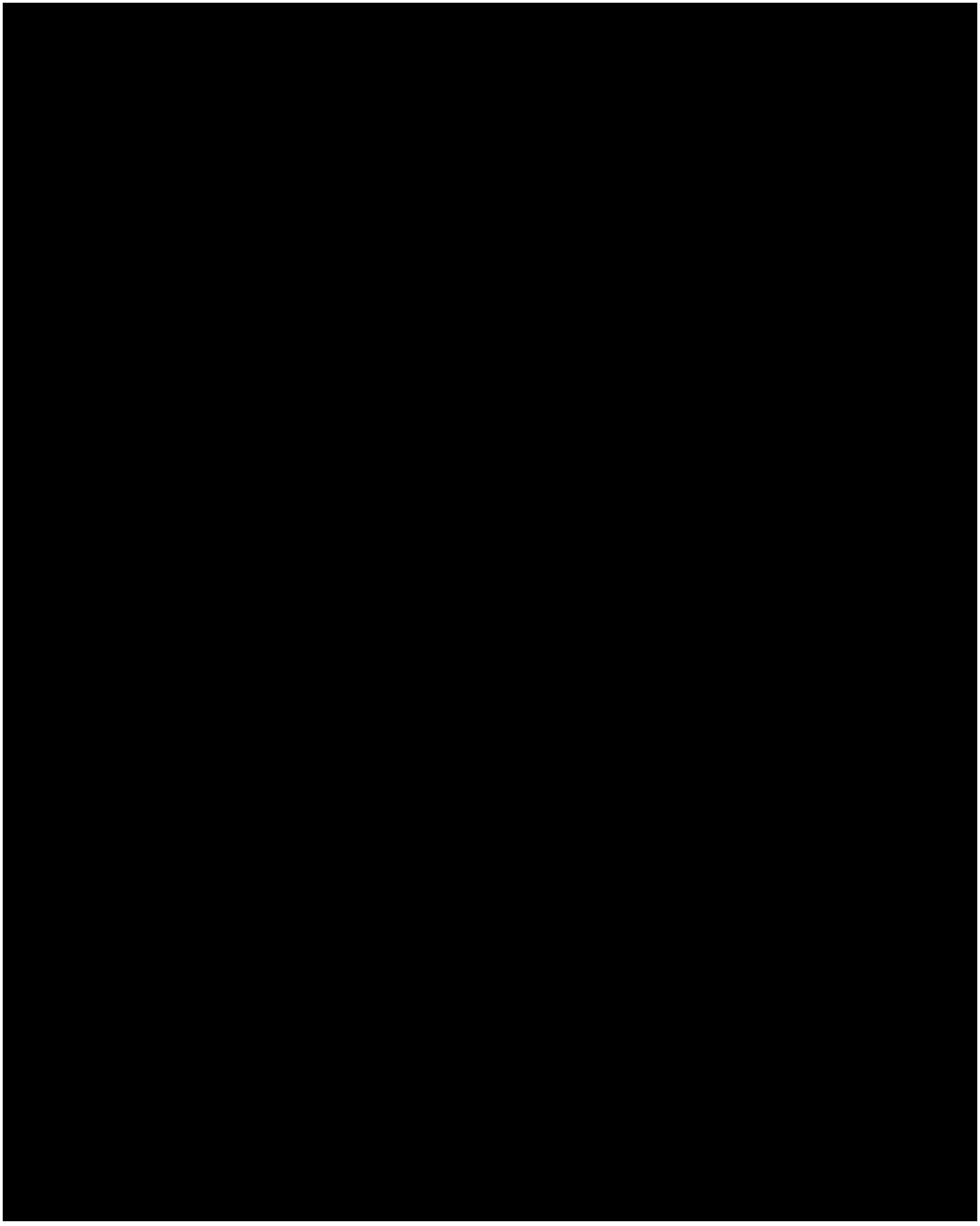
[6] [redacted] *Loeffel Steel Prods. v. Delta Brands, Inc.*, 387 F. Supp. 2d 794 (N.D. Ill. 2005) (refusing to accept the opinion of an expert who "conceded [his] definition was not to be found anywhere else").

[redacted]

Plaintiffs also argue, but fail to support, their assertion that an economic expert is permitted to opine about the import of federal law. [redacted]

Dr. Conti's opinions also fail the reliability test. [redacted]

[7] *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 218 (3d Cir. 2006) ("any testimony as to the legal effect of [federal agency pronouncements], are inadmissible as improper legal opinions."); *United States v. Leo*, 941 F.2d 181, 197 (3d Cir. 1991) (expert's testimony was limited "so that he was not giving his opinion as to what the law required"); *United States v. Universal Rehab Servs.*, 1996 U.S. Dist. LEXIS 7912, at *32 (E.D. Pa. May 31, 1996) ("[expert] did not opine on the ultimate legal issue").



see also Com. v. TAP Pharm. Prods., Inc., 94 A.3d 350, 362 (Pa. 2014) ("[T]his Court is not in need of a body of evidence to apprehend that a rebate operates to reduce the net price of a commodity.").

Plaintiffs attempt to dismiss two on point cases, *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP* and *In re Celexa & Lexapro Mktg. and Sales Practices Litig.*, in which the courts held that damages calculations must take into account the amounts that would have been paid for alternative drugs. 20 F. Supp.

3d 305 (E.D.N.Y. 2014), *aff'd* 806 F.3d 71 (2d Cir. 2015); 325 F.R.D. 529, 540 (D. Mass. 2017). Plaintiffs reject these relevant cases because they "involved fraudulent 'off-label' marketing" that presented a physician with a "decision to prescribe the defendant's drug versus another drug." Pls' *Daubert* Op., p. 23. By contrast, plaintiffs claim their "decision to maintain insurance coverage for the At-Issue Drugs" did not present a "comparative choice," but a "yes-or-no choice." *Id.* This distinction is without support in the record. [redacted][8] [redacted] Because Dr. Conti's damages calculation ignores critical economic realities of the prescription drug market that plaintiffs find inconvenient, it is impermissibly speculative and must be excluded.

II. CONCLUSION

For the foregoing reasons, GSK respectfully requests that the Court exclude opinions and testimony of plaintiffs' experts as set forth herein.

[8] Plaintiffs also point to federal sentencing cases as precedent for this civil damages calculation. Most of these cases are inapposite on their face as they involve products which were physically altered and in some cases defective, rendering them worthless. Five of the cases involved a defective or altered product. *See U.S. v. Milstein*, 401 F.3d 53, 74 (2d Cir. 2005) ("contaminated medicine"); *U.S. v. Gonzalez-Alvarez*, 277 F.3d 73, 76 (1st Cir. 2002) (defendant added salt and water to milk to artificially increase its volume); *U.S. v. Bhutani*, 266 F.3d 661, 670 (7th Cir. 2001) (defendants added a chemical to medicine); *U.S. ex rel. Compton v. Midwest Specialties*, 142 F.3d 296, 298 n.1, 304 (6th Cir. 1998) (brake-shoe kits, "more than 60 percent" of which "were defective."); *U.S. v. Marcus*, 82 F.3d 606, 607 (4th Cir. 1996) ("modify[ing] the [FDA] approved formula [for a drug] by adding two inactive ingredients").

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